JUN - 1 2000

ATTACHMENT 12

510(K) SUMMARY

K00/201

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

April 12, 2000

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **Contact Person:**

Ms. Malgorzata Stanek
Senior Technical Specialist
Phone: (732) 321-3950 Fax: (732) 321-4841

2. **Device Name and Classification:**

Trade Name:	Multix Compact K and Multix L Radiographic X-ray Systems
Classification Name:	Stationary X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1680
Device Class:	Class II
Device Code:	90KPR

3. **Intended Use:**
The Multix Compact K and Multix L Radiographic X-ray Systems allow for radiographic exposures of the body, specifically the skull, spinal column, chest and abdomen, as well as the extremities. Applications can be performed with the patient in the sitting, standing or prone position.

4. **Substantial Equivalence:**
The Multix Compact K and Multix L Radiographic X-ray Systems are substantially equivalent to the Multix TOP/Pro devices which are currently in commercial distribution.

Device	Manufacturer	510(k) Number	Clearance Date
Multix TOP/ Pro	Siemens Medical Systems, Inc.	K971452	5/14/97

5. **Device Description:**
   The Multix Compact K and Multix L units are manually operated, universal x-ray diagnostic systems that include a patient support table (i.e., the Multix Compact K/ Multix L x-ray tables) and standard x-ray components.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**
   The Multix Compact K and Multix L Radiographic X-ray Systems have the same technological characteristics as the predicate device, the Siemens Multix TOP/Pro. The systems contain the same basic configurations with the following standard components: x-ray table, cassette tray, tube supports, x-ray tubes, collimator, wall stand and x-ray generator.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2000

Ms. Malgorzata Stanek
Senior Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K001201
Multix Compact K and Multix L
Radiographic X-ray Systems
Dated: April 12, 2000
Received: April 13, 2000
Regulatory Class: II
21 CFR §892.1680/Procode: 90 KPR

Dear Ms. Stanek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

ATTACHMENT 1

INDICATIONS FOR USE

510(k) Number (if known): K001201

Device Name: Multix Compact K/ Multix L Radiographic X-ray Systems

Indications for Use:

The Multix Compact K and the Multix L Radiographic X-ray Systems allow for radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use_____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001201